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INTERNATIONAL CODES AND YOU

A Reprint by:

VOLUNTARY HEALTH ASSOCIATION OF INDIA

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Preface

VHAI's Involvement in Low Cost Drugs and Rational Therapeutics

The Voluntary Health Association of India (VHAI) is a federation of 15 State Voluntary Health Associations representing over 3000 health projects, institutions and community programmes and participating in a health movement throughout India.

In the various activities of VHAI—community health training, health care and administration education, nursing education, low cost drugs and rational therapeutics—the underlying emphasis has been to generate community supportive programmes that work through the participation of the people. Using creative methods and appropriate technology, the thrust has been towards the creation of a health movement.

In this context, almost all training programmes, publications and other work of VHAI over the last decade have stressed the need for appropriate and low cost health care. The Low Cost Drugs and Rational Therapeutics Programme has focussed on the problems of drug dependency, hazardous and irrational drugs, over-prescribing and bad prescribing practices, "Drug Colonialism" and other related issues such as shortages of essential drugs and the concept of an essential drugs list. In VHAI workshops, alternative forms of drug therapy and even non-drug therapies are discussed and practiced. VHAI's work in drug related issues include a wide spectrum of activities:

- Lobbying for rational drug policies and legislation at the national level
- Campaigning for the production, distribution and dispensing of quality and essential drugs, based on the priorities and health needs of the people
- Encouraging the rational use of drugs and rational pharmacy management at hospitals, health centres, and dispensaries
- On-going education and training of health personnel in alternative health care

- Building awareness among the public of the importance of participating in the maintenance of health.

Some of these activities, seen in a historical perspective, appear as landmarks in the growing concern about drug misuse.

In 1976, Mr Ed Nabert a founder member of VHAI, undertook a study of the Pharmacy in Fr. Muller's Hospital, Mangalore, Karnataka, with a view to finding ways of decreasing drug costs.

In 1978, the Health Care Administration Education team undertook a study of the Tablet Mission Industry, Bangarpet, Karnataka to assess the feasibilty of VHAI's involvement in low cost drug production and distribution, in which the Tablet Mission Industry was engaged. In May 1980, the first Low Cost Drugs workshop was held in Gandhigram, Madurai, under the auspices of the Tamil Nadu Voluntary Health Association.

In June 1981, a special double issue of 'Health for the Millions', VHAI's bi-monthly publication was brought out. This focussed on the major issues related to drugs and spelt out our strategy for further work.

By this time a need was felt to bring together socially conscious individuals from various backgrounds. In January 1982, a group of consumer activists, pharmacologists, doctors, journalists and community health coordinators, met in Pune to review the drug situation in India and draw up concrete action plans.

At the Pune Workshop, it was decided to take up the 'Hormonal Pregnancy Test' issue, better known as the 'E P Drug Campaign' (E P—high dose Estrogen Progesterone combinations). This was to be the campaign theme for the 8th March, International Women's Day. Numerous individuals and women's groups, journalists and health groups pooled their efforts and helped build public pressure which led to the banning of these products by the drug control authorities.

Another workshop was held in August 1982, in Jaipur—a VHAI-MFC collaboration—and this time the focus was on hazardous and irrational drugs and the need to support the new Bangladesh drug policy.

At an Organizational Development Seminar in Pune, October 1982, a smaller group met to discuss and critically study the IFPMA Code, which was widely circulated for comments and awareness-building.

A Drugs Newsletter was circulated periodically to keep the groups informed about the rapid changes in the drug scene and of our own activities.

In April 1983, we had a number of meetings with two distinguished visitors, Dr Olle Hansson, the famous Paediatrician-Neurologist from Sweden, who first reported the existence of Optic Neuritis as a side effect of Clioquinol, and Mr Etsuro Totsuka the Japanese attorney who successfully fought in the Tokyo District Court on behalf of the victims of SMON (Subacute myelo optic neuropathy—the syndrome of crippling and blinding caused by Clioquinol.)

In April 1983, the drug issue was again highlighted during a seminar, (organized by VHAI and other organizations), on the Statement of the National Health Policy. A nucleus of socially conscious individuals in different parts of India and abroad has slowly evolved into a larger movement for health rights. Each person, whether he is a health professional or a consumer, has a role to play in this movement, be it in a big way or small.

We all share a common concern regarding the unavailability of essential and life saving drugs so urgently required for the nation's real health needs and the almost total lack of basic health care for the majority of our people.

VHAI has based its work on linkages with other groups and organizations working on similar lines. Some of these organizations are the Medico Friends Circle (MFC), Arogya Dakshata Mandal, Pune; Kerala Sastra Sahitya Parishad, Trivandrum; Consumer Education and Research Centre, Ahmedabad; Consumer Guidance Society of India and Centre for Educa-

tion and Documentation, Bombay; Centre for Science and Enviornment, Delhi; Federation of Medical Representatives Associations of India, Patna; and others.

Through the combined efforts of these concerned individuals and groups, an informal Drug Action Network has emerged to confront these issues at the national level.

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Acknowledgements

If the Drug Action Network has grown from a small nucleus of individuals seriously concerned about the misuse and dumping of drugs in this country to a nationwide front — an expression of the growing awareness about drug related health problems — it has been through the consistent efforts of individuals and organizations throughout the country. It would not be out of place to acknowledge their contribution and emphasise their role in the movement.

In particular, all the participants of Drug Workshop I in Pune, had a significant contribution to make in setting the ball rolling, especially with the E P Forte campaign. Dr Palaniappan of Kilpauk Medical College; Mrs Bhanumathy from Madras, Ms Vimal Balasubramaniam, Hyderabad; the activists of SAHELI, Delhi; Dr Anant Phadke, Medico Friends Circle, Dr. Rane, Arogya Dakshata Mandal, Pune; Pramod Kulkarni (CERC), Ahmedabad; Rajeev Gupta (CSE), Delhi; Rajiv Tiwari and Mukarram Bhagat (CED), Bombay, worked closely with us on this campaign.

The network has received consistent support from journalists throughout the country. The articles and features by Claude Alvares, Shehnaz Ankleswaria, Kamla Mankekar, Sevanti Ninan, Ayesha Kagal, Kajal Basu and others in the national press have contributed significantly in raising public awareness about these issues.

On the legal front Mr and Mrs Hingorani, Fr P D Mathew, Vincent Panikulangara and others have taken the battle to the courtroom and for the first time have raised these issues in the Supreme Court.

We are grateful to our friends across the seas, Eva Lachkovics and Virginia Beardshaw (IOCU), Dr John Yudkin, Dr Andrew Herxheimer, Dr Olle Hansson, Mr Etsuro Totsuka and in turn to their friends and contacts, for their generous assistance in providing us with information, very often of a highly technical nature.

Acknowledgements are also due to all those individuals and organisations who have inadvertantly remained unnamed above, but whose contribution and support to the network has been and continues to be invaluable.

Last but not the least is the contribution of the entire staff at VHAI especially S. ("Chinu") Srinivasan and Dr C Sathyamala for their role in the drug campaigns, and all the rest for their unstinting support, which made every handout, newsletter, workshop and campaign a successful and rewarding experience.

Dr. Mira Shiva M.D.

Introduction

This paper is a reprint by the Voluntary Health Association of India (VHAI) of two proposals for an International Code on Pharmaceutical Marketing—one drafted by the International Federation of Pharmaceutical Manufacturers' Associations (IFPMA), the other by Health Action International (HAI), an informal network of consumer, development action and other public interest groups.

The need for international control of trade in Pharmaceuticals is quite clear. A World Health Assembly resolution in May 1978 requested the Director General of the WHO (World Health Organization) to develop a code of marketing practices, with special emphasis on the supply of essential drugs for developing countries. Despite continued pressure from a number of WHO member governments, nothing has been done.

In this vaccum, the drug industry, through its International Federation, the IFPMA launched a voluntary code in 1981—evidently an attempt to forestall independent regulation. Though the IFPMA does not state why it decided to introduce a code at this particular time, the following factors would certainly have been important:

1 *There has been considerable criticism of the activity of the international pharmaceutical industry, and it appears to be increasing.* The industry has given little evidence to suggest that it accepts such criticism—but would certainly be aware, at least, that health-care professionals increasingly find it legitimate and to the point. The relative success of the campaign coordinated by the International Baby Food Action Network (IBFAN) has demonstrated the potential for international action my media, consumer, public interest and development and health action groups—particularly where developing countries are concerned.

2 *The need to avoid further statutory regulation of the industry at either national or international level.* The indications are that the IFPMA proposed its Code in response to the threat of a move by the World Health Assembly

to work towards the setting up of a formal International Code of Pharmaceutical Marketing Practice. In the event, the threat did not materialise at the summer 1981 World Health Assembly—but there remains the possibility of future initiatives, if not through the World Health Organization or UNCTAD, then possibly through the UN Centre on Transnational Corporations.

3 *The credibility of the industry-now clearly under threat—is a vital commercial asset.* Lack of confidence in the drug industry by those who regulate, prescribe or use pharmaceutical products could be commercially disastrous. It is clearly critical that the industry generally, as well as individual drug companies are trusted and seen to 'care'.

The IFPMA has responded to these (and perhaps other) imperatives by first issuing a statement of the 'the obligations' of the pharmaceutical industry; and secondly, suggesting a number of 'general principles' by which these obligations might be fulfilled.

It is important to recognise that, in doing so, the IFPMA is not trying to introduce its own 'simple world code'. The IFPMA specifically says this would be 'impractical' because of differences in local conditions. All IFPMA is trying to do with its Code is 'to encourage' national member organizations either to introduce or to revise their own voluntary codes.

What is published in the first half of this reprint is a detailed critique of the industry code, explaining its many weaknesses. For example: the industry code largely ignores the need for both monitoring and proper enforcement.

In contrast, HAI's draft code tries to be comprehensive. It has been prepared by HAI to encourage constructive discussions between all parties involved in the supply and use of pharmaceuticals, which should lead to the development of controls acceptable to everyone concerned. It suggests standards for drug promotion, pricing, sales, distribution, trade, technology, and research and development. The HAI proposals were first formally

presented to the United Nations Conference on Trade and Development (UNCTAD) Committee on Transfer of Technology in November 1982. HAI was asked to do this by representatives of developing countries on this committee.

Individual groups may think of alternative or additional requirements which might be needed to control abuse in pharmaceutical marketing, and consider how such requirements might effectively be enforced at both national and international level. Groups might also wish to collect examples of apparent malpractices.

Collectively, groups may find it useful to exchange information on the design and enforcement of standards under different voluntary (self regulatory) systems operating in their countries. Groups might also wish to compare and pool the evidence they obtain about apparent malpractices and to publish and publicise this evidence both locally and internationally.

We invite and welcome comments and/or questions related to these issues.

Please write to:

Low Cost Drugs and Rational Therapeutics Cell
Voluntary Health Association of India
C-14, Community Centre
Safdarjung Development Area
New Delhi-110016

OR

HAI Clearing House c/o IOCU
Post Box 1045
Penang, Malaysia.

The IFPMA Code of Pharmaceutical Marketing Practice March 1981

Preamble

The Statute of the Federation article 3 states that one of the objects of the Federation is "to promote and support continuous development throughout the pharmaceutical industry of ethical principles and practices voluntarily agreed on " and "to coordinate the efforts of its members towards the realization of the above subjects"

It is believed that in keeping with the pharmaceutical industry's international responsiblities, the members of the Federation will be prepared to accept certain obligations, insofar as their marketing practices are concerned, and to ensure respect for them.

IFPMA recommends a Code of Marketing Practices to its member associations, recognizing the difficulty of setting out a simple Code which will be applicable in all parts of the world. It seems clear that national and regional conditions and legal restrictions will continue to vary to such an extent as to make a simple world Code impractical. Nevertheless, the Federation believes that it has a duty to encourage its member associations to either introduce such Codes of Practices or where such Codes already exist, to continually re-examine and where necessary revise them so that a voluntary system based on such a Code keeps pace with modern medical knowledge and changing health services and conditions.

It is recognized that many individual member associations of IFPMA have laid down their own Codes of Marketing Practices and this recommended Code is not intended to replace similar Codes or instruments already in force by members of the Federation. The following voluntary Code is therefore put forward as a model for IFPMA's member associations.

A Code of Marketing Practices of this sort should be the responsibility of member associations who should also provide guidance to their members on matters of compliance and interpretation.

Obligations of Industry

The obligations of the industry may be identified as follows:

The pharmaceutical industry, conscious of its special position arising from its involvement in public health, and justifiably eager to fulfil its obligations in a free and fully responsible manner, undertakes:

- to ensure that all products it makes available for prescription purposes to the public are backed by the fullest technological service and have full regard to the needs of public health;

- to produce pharmaceutical products under adequate procedures and strict quality assurance;

- to base the claims for substances and formulations on valid scientific evidence, thus determining the therapeutic indications and conditions for use;

- to provide scientific information with objectivity and good taste, with scrupulous regard for truth, and with clear statements with respect to indications, contra-indications, tolerance and toxicity;

- to use complete candour in dealings with public health officials, health care professionals and the public.

Suggested Code of Marketing Practices

'We hereby declare our intention to voluntarily conform to the following Code of Marketing Practices:

I General Principles

1. The term "pharmaceutical product" in this concept, means any pharmaceutical or biological product intended for use in the

diagnosis, cure, mitigation, treatment or prevention of disease in humans, or to affect the structure or any function of the human body, which is promoted and advertised to the medical profession rather than directly to the lay public.

2. Information on pharmaceutical products should be accurate, fair and objective, and presented in such a way as to conform not only to legal requirements but also to ethical standards of good taste.

3. Information should be based on an up to date evaluation of all the available scientific evidence, and should reflect this evidence clearly.

4. No public communication shall be made with the intent of promoting a pharmaceutical product as safe and effective for any use before the required approval of the pharmaceutical product for marketing for such use is obtained. However, this provision is not intended to abridge the right of the scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media, nor to restrict public disclosure to stockholders and others concerning any pharmaceutical product as may be required or desirable under law, rule or regulation.

5. Statements in promotional communications should be based upon substantial scientific evidence or other responsible medical opinion. Claims should not be stronger than such evidence warrants. Every effort should be made to avoid ambiguity.

6. Particular care should be taken that essential information as to pharmaceutical products' safety, contra-indications and side effects

or toxic hazards is appropriately and consistently communicated subject to the legal, regulatory and medical practices of each nation. The word "safe" must not be used without qualification.

7. Promotional communications should have medical clearance or where appropriate, clearance by the responsible pharmacist, before their release.

II Medical Representatives

Medical representatives must be adequately trained and possess sufficient medical and technical knowledge to present information on their company's products in an accurate and responsible manner.

III Symposia, Congresses and other Means of Verbal Communication

Symposia, congresses and the like are indispensable for the dissemination of knowledge and experience. Scientific objectives should be the principal focus in arranging such meetings, and entertainment and other hospitality shall not be inconsistent with such objectives.

IV Printed Promotional Material

Scientific and technical information shall fully disclose the properties of the pharmaceutical product as approved in the country in question based on current scientific knowledge including:

- The active ingredients, using the approved names where such names exist.
- At least one approved indication for use together with the dosage and method of use.
- A succinct statement of the side-effects, precautions, and contra-indications.

Except for pharmaceutical products where use entails specific precautionary measures, reminders need not necessarily contain all the above information providing that a form of words is used which indicates clearly that further information is available on request.

Promotional material, such as mailings and medical journal advertisements, must not be designed to disguise their real nature and the frequency and volume of such mailings should not be offensive to the health care professionals.

V Samples

Samples may be supplied to the medical and allied professions to familiarize them with the products, to enable them to gain experience with the product in their practice, or upon request.

Critique of the IFPMA Code

Extract from "Not to be taken—Worthless" by Health Action International

The 'FPMA omits the three essential ingredients of any code of practice.

What the IFPMA has produced is considerably less authoritative than a code of practice. The IFPMA makes no reference in its statement to any of the following *essential* ingredients in any code—other than to suggest that these may be matters for the individual national member organisations:

1. *Need for interpretation.* Almost all of the suggested provisions of the IFPMA Code are very general—and their significance in practice must therefore very largely depend on how they are interpreted and by whom. The IFPMA statement gives little or no evidence of thought on this point. For example:

- The preamble of the Code refers to the need to ensure that the industry makes products which 'have full regard to the needs of public health'—a statement so vague that it is hard to accept it as anything much more than an advertising or public relations slogan. It could on the other hand be taken to mean that member organisations were expected, as a general rule, to market only essential drugs in developing countries. But this is clearly not intended, for the consensus of

authoritative and informed opinion is that the multinational drug industry (the backbone of the IFPMA membership) markets many products which are either useless, positively undesirable or actually dangerous, given the ways in which they are promoted and/or used in practice.

- Another specific provision in the IFPMA Code is that 'medical representatives must be adequately trained and possess sufficient medical and technical knowledge to present information on their company's products in an accurate and responsible manner'. This seems fine so far as it goes – but it does not go very far. Thus, the voluntary Code of the Association of the British Pharmaceutical Industry (which is an IFPMA member) makes the same general requirement – but then adds 30 or so further paragraphs to interpret and spell out more precisely what the basic requirement is intended to mean.

2. *Need for monitoring.* What assurance is there that what pharmaceutical companies do in practice will comply with the provisions of the IFPMA Code? Is the Code to operate as the basis of a complaints procedure; or is there to be monitoring of industry practice by those responsible for the operation of the Code? The significance of this is fundamental: if there is no mechanism for complaints handling and none for monitoring, how can one be sure that the provisions of the Code are worth more than the paper they are written on?

There is no indication from IFPMA that its Code is intended as the basis of a complaints procedure. Nor is there any reason to believe it would be effective if it were – and not the least because the Code makes so many general provisions whose real significance is far from clear.

While the processing of complaints might be an indispensable part of a control system, it is clearly no substitute for a properly planned programme of monitoring. It seems essential that particular kinds of marketing practice

are systematically examined – not only to seek out infringements of the Code, but to establish the need for revision of the Code or for new provisions.

In the end, the success or failure of any voluntary code – if it is to be operated in any sense 'in the public interest' – must depend on systematic monitoring, to obtain aggregated evidence of representative industry practice. The IFPMA statement makes no reference to the need for monitoring at all.

3. *Need for enforcement.* Another critical factor – to which no reference is made in the IFPMA statement – is what happens when and if there is *prima facie* evidence that the Code has been violated. This is another serious omission, for among the factors which will determine how effective the Code will be in practice are:

- Whether the industry (through its association, or otherwise) acts as a 'judge in its own cause' – or whether enforcement decisions are taken by truly independent elements.

- Whether enforcement decisions are published – or taken and made in secret. Is it possible to establish, on the basis of past decisions, what practices are acceptable or unacceptable? And what can be learned about the record of individual companies in complying with provisions of the code?

- What sanctions are, or might be applied to companies which break the provisions of the code – either on isolated occasions, or more regularly? If sanctions are not applied, what incentive is there for firms to observe the requirements of the code?

here is one last point worth making about voluntary codes of practice, in eneral – and it applies even when such codes do make some provision for

interpretation, monitoring and enforcement. The point is simply that, by their nature, voluntary codes do not work well, or do not work at all.

The reasons for this seem almost self-evident, when explained in the terms used by Geoffrey Chandler when he was a Director of Shell International. Chandler (now Director of the UK's National Economic Development Office) stated that: 'Codes of conduct tend to be placebos which are likely to be less than a responsible company will do of its own volition and more than an irresponsible company will do without coercion.'[3]

More charitably, the Director of the Harvard University Multinational Enterprise Project, Professor Raymond Vernon, has suggested that 'there is nothing wrong with an approach of this sort...' though he continued by saying 'it is trivial in comparison with the malaise with which it deals.'[4]

Obligations of the pharmaceutical industry.

To summarise, what the IFPMA has called its 'code of practice' is not recognisable as such – but even if it were, its significance would be expected to be slight. As it is, the IFPMA claims no jurisdiction – and gives no indication that it could or would take action, even if its suggested provisions were persistently and flagrantly breached.

Having said this, there are some things that can and should be said emphatically in favour of some of the statements made by IFPMA. What the IFPMA has suggested as standards may not be enforceable – but it is clearly an advance to have some suggested standards, rather than none, if only as useful points of reference.

More than this, some of the statements made by IFPMA – and in particular those relating to provision of information – are very welcome indeed – because they legitimise and may even raise independent observers' expec-

tations of the drug industry.

For instance, *in principle,* there would be complete agreement between **Health Action International** and the International Federation on what IFPMA has defined as one of the principal 'obligations of the industry', namely:

> 'to use complete candour in dealings with public health officials, health care professionals and the public.'

As members of the public, whatever else, HAI groups could ask for nothing more – but, equally, should be satisfied with nothing less.

Other standards suggested by IFPMA have points to commend them, though they generally fall short of the unequivocal promise of the provision above. It is worth commenting very generally on some of the other points suggested as 'obligations of the industry':

Obligation: *'To ensure that all products it (the industry) makes available for prescription purposes are backed by the fullest technological service and have full regard to the needs of public health'.*

Comment: On the face of it, this would seem important and appropriate – but it is unfortunately so vague as to be valueless. In particular, the phrase 'full regard to the needs of public health' has little meaning unless it takes fully into account the conditions typical of many developing countries, where prescription drugs are freely available over-the-counter and widely used for self-medication.

Obligation: *'To produce pharmaceutical products under adequate procedures and strict quality assurance'*

Comments: Again, the implied intention is admirable, but vagueness is a serious problem. What does 'adequate' mean for example? If it means 'in compliance with local law', for instance, then it may be anything but adequate.

It is notable that there is no reference to the industry's obligations, in case of accident or oversight. If defective products are found to have been distributed – and *every* drug manufacturer has experienced this – then what is to be done? Are companies under an obligation to notify the proper authorities and/or doctors and distributors; and/or to arrange and publicise a recall, and to remedy the damage done?

Obligation: *'To base the claims for substances and formulations on valid scientific evidence, thus determining the therapeutic indications and conditions of use.'*

Comment: To fulfil the obligation to use 'complete candour' in its dealings, the industry would have to go further than this. It is not enough to base its claims on valid evidence. The industry would have also to take account of valid evidence which conflicted with its claims.

Obligation: *'To provide scientific information with objectivity and good taste, with scrupulous regard for truth, and with clear statements with respect to indications, contraindications, tolerance and toxicity.'*

Comments: If the object of such a provision is to see maintained 'a scrupulous regard for truth', it should apply to all information put out by companies – ie, in advertising and promotional literature.

> As a more general point, independent observers with experience of the industry may consider this stated ideal so far removed from reality that it strains credulity to breaking point or further.

Because the IFPMA Code is so vague and difficult to interpret, no specific comment will be made about the individual provisions listed as a 'suggested code' (see Appendix). We see these as a very disappointing ragbag of requirements – about which two general observations should suffice.

First, there are serious gaps and omissions in the suggested requirements – and specifically, the lack of any reference to 'gifts and inducements' is breathtaking. Equally, little or nothing has been said about the content of advertising, methods of promotion, or product liability.

Secondly, the terms of some other requirements are so broad and apparently undemanding, that it seems safe to assume they are likely to change nothing. The IFPMA's suggested provision on 'sampling' clearly illustrates this. It says:

> *Samples may be supplied to the medical and allied professions to familiarise them with the products, to enable them to gain experience with the product in their practice, or upon request.'*

There is nothing even in this paper requirement that could be expected to control what is a widespread and corrupting influence in world medicine. In developing countries, in particular, the problems caused by sampling are especially acute: in India, for example, an official Government Committee has commented (1975) that the scale of sampling is 'lavish' and has 'degenerated into a rat race among manufacturers'.[5] There seems no reason to suppose that the IFPMA Code would be effective in controlling this or many other examples of malpractice.

Update: the position in May 1982

The statement above was published by Health Action International in September 1981 – at the time of the release of the IFPMA's own Code. In the six months following publication, several developments took place which further underlined HAI's criticisms of the IFPMA Code.

First, it is worth referring to the assessment of the IFPMA Code made by Dr. H. Schwartz, writing in the US industry newsletter, *Pharmaceutical Executive,* August 1981. This makes it quite clear that the IFPMA Code was indeed introduced mainly to forestall regulation of the pharmaceutical industry, in particular by the World Health Organisation. According to Dr. Schwartz, the Code was introduced by the IFPMA to repel 'a coming WHO effort to impose unacceptable controls over all pharmaceutical commerce in the Third World'. In the light of what Dr. Schwartz goes on to say, it is quite clear that it would be naive for anyone to take the IFPMA's effort seriously as a Code:

> 'The Code pledges the industry to provide high quality products, to base its claims on valid scientific evidence regarding indications and conditions for use, to provide full scientific information with scrupulous regard for truth in all matters (including contraindications and toxicity), and to use complete candour in dealing with government health officials, physicians, nurses, other health providers and the public.
>
> To some, this may sound like a pledge in favour of motherhood and against cancer. But the real political question is whether the code will be adequate to defeat the forces against private enterprise within WHO.'

Though the US Pharmaceutical Manufacturers Association has also made it clear[6] that the IFPMA Code is to be regarded as a political (rather than therapeutic) tool, other parts of the international pharmaceutical industry appear to have accepted the Code more at face value. In particular, the Swedish industry organisation, LIF, publicly expressed its doubts about the purpose and value of the provisions of the Code, within weeks of its

publication. Above all, LIF was anxious about the design of the Code's provisions, and their intended purpose: 'It is in our opinion absolutely necessary to clarify beyond doubt the nature of the proposed Code, and for whom the Code is proposed.....'[7]

In response to these and other criticisms, the IFPMA issued a 'Supplementary Statement' to the Code, in March 1982.[8] Its purpose was said by the IFPMA 'to demonstrate the industry's commitment to the observance and monitoring of the code' though without varying 'in any way the provisions of the original document'[9] The IFPMA's statement consisted of four paragraphs which are reproduced – with our comments – below:

1. *Major pharmaceutical multinational companies belonging to IFPMA member associations, have been asked to commit themselves to the observance of the code wherever they market their products.*

Comment: It seems very surprising that the major pharmaceutical companies had not been asked for such a commitment before the IFPMA Code was first published – since their cooperation would be vital to the operation of the Code. However, the important thing is not that these companies have now been asked to cooperate – it is whether these companies will agree to do so, and what difference it will make to their future conduct. It is, we think, now up to the IFPMA to state specifically which companies have been asked for a commitment, and how they have responded. It would also be useful to learn more about the commitment expected from other companies, whose cooperation has not been specifically sought.

2. *To meet the criticism that many Third World countries are not aware of the indications, contraindications, side-effects, etc, of individual drugs that have been accepted in the developed countries, IFPMA will offer to supply free of charge to government health departments of Third World countries, copies of up-to-date standard compendia such as The Physician's Desk Reference (USA), the ABPI's Data Sheet Compendium (UK), the Rote*

Liste (Federal Republic of Germany) and the Dictionnaire Vidal (France).

Comment: We know of no criticism of the kind referred to; and suggest that the IFPMA offer is wholly spurious. It seems inconceivable that any country which lacked the elementary texts referred to would be in any position to control the drug industry, even if they were supplied with these books. In any case, it is completely inconsistent for the IFPMA to suggest here that health departments 'in many Third World countries' lack these basic resources – when the IFPMA goes on to argue (in point 4) that the drug regulatory procedures 'in many Third World countries' effectively dictate the industry's drug promotional policies. The regulatory procedures in these 'many Third World countries' cannot be both completely inadequate and wholly compelling at the same time.

3. *The following procedure has been agreed to deal with alleged breaches in the observance of the code: IFPMA member associations have been recommended to set up their own separate procedures for monitoring such complaints; many of the major associations have already done this. A procedure has also been agreed to deal with complaints received by IFPMA itself, and an ex officio committee of IFPMA's Council consisting of the President, the two Vice-Presidents and the Executive Vice-President will oversee all IFPMA matters involving the code. The major sanction against any company that transgresses the code will continue to be the sanction of adverse publicity. However, IFPMA wishes to stress that its main objective and that of its member associations will be to effect, as rapidly as possible, the correction of any proven breaches in the observance of the code.*

Comment: The almost complete lack of detailed information about the monitoring and enforcement procedures alluded to here underlines the criticism made earlier in this report. Nevertheless it is worth pointing out:

(a) The IFPMA says that many of the 'major associations' have already set up procedures for monitoring complaints. However,

(a) The IFPMA says that many of the 'major associations' have already set up procedures for monitoring complaints. However, these major associations are almost exclusively based in the industrialised countries – when the need for effective regulation is in the Third World. HAI invites the IFPMA to publish details of all monitoring schemes now operating in developing countries.

(b) The procedure which the IFPMA itself will use to deal with complaints is not explained. However, it is clearly very unsatisfactory that the Committee involved should comprise only industry personnel – who violate the principles of natural justice in acting as judge in their own cause. The IFPMA should be looking towards representation by a majority of independent elements, including representatives of Third World countries for whose benefit the IFPMA scheme is supposedly run.

(c) The reference to the 'major sanction of adverse publicity' is not at all convincing. HAI understands that this sanction has in fact been very rarely if ever used by IFPMA member associations – but again, we invite the IFPMA to state publicly on what occasions such adverse publicity has been given.

4. *Comments have been made from time to time about the problem that industry faces in providing uniform information world-wide on labelling, packaging leaflets, data sheets and general advertising claims. The industry's position on the important matters of information on scientific claims, contra-indications and side-effects is set out in the code itself. This makes it clear that labelling, packaging leaflets, the information and data sheets and advertising claims should be consistent with the body of scientific and medical evidence pertaining to that product. This should be interpreted as meaning that such information given in Third World countries, should be consonant with what is being done in the companies' markets in the developed world. However, it should be borne in mind that countries which have*

their own regulatory procedures (and this includes many Third world countries) may well dictate a non-uniform approach to such matters, which industry has no option but to follow.

Comment: This adds little or nothing to the vague generalisations to be found in the main part of the IFPMA Code. This supplementary statement makes no reference to drug information published in commercial prescribing guides. It suggests no requirement for the information to be given with medicines marketed only in developing countries. It does not define the meaning of the all-important words 'consonant' and 'consistant' and – for the reasons given above – it also over-emphasises to an absurd extent the responsibilities of Third World governments. The primary responsibility for the supply of adequate drug information undoubtedly lies with the industry itself.

Text references

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3. **The Guardian** (UK) 5 January, 1973
4. Vernon R.: **Sovereignty at Bay** (New York: Basic Books, 1971). p.264
5. **Report of the Committee on Drugs and Pharmaceuticals.** Chairman: Shri Jaisukhlal Hathi. (New Delhi: Ministry of Petroleum and Chemicals, Government of India, April 1975).
6. The PMA's position is discussed in detail in Medawar C. and Freese B.: **Drug Diplomacy** (London: Social Audit, 1982) pps.57-63).
7. SCRIP No.652 16 December 1981, p.1. See also SCRIP No.650, dated 9 December 1981
8. SCRIP No.674 10 March 1982, p.10.
9. Ibid. The quote is from SCRIP rather than directly from the IFPMA

HAI—A Draft International Code on Pharmaceuticals

Preamble

The participating countries:

1. Reaffirming that good health is a fundamental human right;

2. Recognising that governments have a responsibility for ensuring the health of their people;

3. Recalling that a main social target of governments, international organizations and the whole world community in the coming decades should be the attainment by all the peoples of the world by the year 2000, of a level of health that will permit them to lead a socially and economically productive life;

4. Convinced that the promotion and protection of the health of the people is essential to sustained economic and social development;

5. Drawing attention to the fact that provision of an adequate supply at reasonable cost of essential drugs is, among other things, a prerequisite for the promotion and protection of the health of the people;

6. Aware that a majority of the world's population, particularly those in the rural areas and urban slums of developing countries, does not have regular access to even a few essential drugs necessary for primary health care whilst the drug bills in these countries may account for up to 40—50 per cent of the total health expenditure;

7. Affirming the right of every sick person to have access to essential pharmaceuticals;

8. Considering that a limited number of transnational corporations based in developed countries manufacture almost 90 per cent of the world output of pharmaceuticals and control drug technology and world trade and that the existing system of marketing practices of these corpora-

tions is inappropriate to meeting the health needs of the people , particularly in developing countries;

9. Bearing in mind that in a number of instances the prices of pharmaceuticals do not relate to the actual cost of manufacture but are determined by what the market can bear;

10. Drawing attention to the fact that there are wide discrepancies in the prices of drugs on the world market which cannot be explained by market forces;

11. Recognising that the pharmaceutical industry is characterised by an unusual degree of market power;

12. Recalling that the non-aligned and other developing countries have expressed an urgent desire to reform the existing system for the procurement and provision of pharmaceuticals;

13. Taking into consideration that a large number of developing countries have already established local manufacture of pharmaceuticals and are purchasing pharmaceutical technology on the world market and that some of them are forced to pay exorbitant amounts of foreign exchange for their technology imports;

14. Convinced that the development and strengthening of indigenous technological capacity in the pharmaceutical sector is critically dependent on ongoing research and development activities and that a research base in developing countries is necessary to insure against underdevelopment;

15. Believing that certain fundamental principles associated with trade and technology in the pharmaceutical sector transcend national and regional boundaries and are universally applicable;

16. Recognising that the indispensable role of pharmaceuticals in the con-

trol of disease and the prevention of human suffering distinguishes them from other consumer goods which are subject to the laws of supply and demand;

17. Believing that, in the light of the foregoing considerations, an International Code of Pharmaceutical Marketing Practices, including norms on promotion, pricing, sales, distribution, trade, technology, research and development, in the pharmaceutical sector would, under mutually agreed and advantageous terms to all parties, enable all participating countries—particularly developing countries—to provide to all their people, safe and effective essential drugs at prices they can afford.

18. Agree on the adoption of the following International Code of Pharmaceuticals Marketing Practices.

Article 1: Aim of the Code

The aim of this Code is to enable consumers, particularly those from the developing countries, to procure safe and effective pharmaceuticals essential to their real health needs, at costs they can afford.

Article 2: Scope of the Code

2.1 This Code shall apply to all international activities connected with the procurement of pharmaceuticals and pharmaceutical technology.

2.2.1 The Code applies to the following activities associated with the pharmaceutical sector: drug registration; registration of new drugs: pre-registration clinical trials of new drugs; provision of information; labelling, package inserts and promotional material; sales promotion of pharmaceutical products; pricing, sales and distribution; pharmaceutical technology; research and development.

Article 3: Definitions

3.1 "Active substance": That portion of a drug product intended to produce a therapeutic effect.

3.2 "Adverse reaction": A reaction to a drug which is noxious or unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the modification of physiological function.

3.3 "Advertisement": Any representation conveyed by any means whatever for the purpose of promoting directly, or indirectly, the distribution or sale of any drug.

3.4 "Auxiliary pharmaceutical substance": A substance added to the active substance to give the latter suitable consistency so that a convenient dosage form can be formulated.

3.5 "Benefit/risk ratio": The ratio of benefit to risk in the use of a drug: a means of expressing a judgement concerning the role of the drug in the practice of medicine, based on efficacy and safety data along with consideration of misuse potential, severity and prognosis of the disease, etc. The concept may be applied to a single drug or in comparing two or more drugs used for the same indication.

3.6 "Clinical trial": A procedure for comparing the relative advantages and disadvantages of one drug with another by administering them according to a planned protocol to a group of patients under controlled conditions.

3.7 "Contra-indications": Conditions which make the administration of a drug positively harmful. These conditions include diseases, physiological states (eg pregnancy, lactation) and specific groups (neonates, infants).

3.8 "Drug" (synonymous with "pharmaceutical product"): Any substance or a mixture of substances that is manufactured, sold, offered for sale or represented for use in: (i) the treatment, mitigation, prevention or diagnosis of disease, an abnormal physical state or the symptoms thereof in humans or; (ii) the restoration, correction or modification of organic functions in humans.

3.9 "Drug registration": The term used for the procedure of release, compliance or approval for marketing after a drug has undergone the process of drug evaluation (by a competent health authority).

3.10 "Efficacy": The ability of a drug to produce the purported effect as determined by scientific methods.

3.11 "Ethical drug": A drug that can be purchased only after obtaining a valid prescription for it from a medical doctor or other authorised health personnel. This is also referred to as a "prescription drug"

3.12 "Interactions": A noxious or unintended reaction which occurs when two or more drugs are administered simultaneously at normal doses. This term also refers to similar reactions between a drug and food taken together.

3.13 "International non-proprietary name" (INN): This is the official name assigned to a drug by the World Health Organisation and is internationally recognized. It is also known as a generic name.

3.14 "Label": A display of written, printed or graphic matter upon the immediate container or the outside container or wrapper of a drug package.

3.15 "Marketing": Product promotion, distribution, sales, advertising, product public relations and information services.

3.16 "New drugs": A drug which has not been previously registered or

marketed for medical purposes, including any new salts and esters of an active substance, new fixed combinations of substances previously marketed, or of any drug previously marketed if its indications, mode of administration, or formulation, are changed.

3.17 "Over the counter drug": A drug that can be purchased without a prescription from a medical doctor or other authorised health personnel. This is also referred to as a proprietary drug.

3.18 "Package insert": A leaflet containing specified relevant information on a drug included in every package containing that particular drug.

3.19 "Pharmaceutical manufacturers": All persons involved in the production of a drug, including processing, compounding, formulating, filling, packing, repacking, altering, finishing and labelling with a view to its storage, sale and distribution.

3.20 "Pharmaceutical traders": All persons involved in the process of import, storage, sale and distribution of drugs whether as wholesalers or retailers.

3.21 "Purity": The degree to which other chemical or biological entities are present in any substance.

3.22 "Sample": Single or small quantities of a product supplied without cost.

3.23 "Side-effects": Expected but noxious or unpleasant effects produced by a drug at normal doses.

3.24 "Trade name" (also called brand name): This is a name given to a drug by the manufacturer which if registered and protected under national legistation, can be used exclusively by the manufacturer to distinguish his product from other products containing the identical active chemical substance or substances.

Article 4: Drug registration

4.1 All pharmaceutical products, both ethical drugs and over-the-counter (OTC) preparations offered for sale in a country, should be duly registered by a competent authority in that country.

4.2 Pharmaceutical manufactures and traders will abstain from making available in a country pharmaceutical products which are not registered in that country.

4.3 Pharmaceutical manufacturers and traders must provide the national registration authorities with all the information available to them on a pharmaceutical product, including all information they have given to countries with an efficient drug registration system, even if all this information has not been requested by the registration authority.

4.4 Pharmaceutical manufacturers and traders must provide the registration authority with a list of all countries in which the specific product has not been accepted for registration.

4.5 Pharmaceutical manufacturers and traders should inform the registration authority if a pharmaceutical product already registered in that country has been removed from the register of any other country together with the reason for its removal.

4.6 Pharmaceutical manufacturers and traders, when applying for registration of a product, must undertake that subsequent to the product's registration they will provide the registration authority and consumers with all new information they receive on its effects, adverse reactions and interactions.

Article 5: Registration of new drugs

5.1 Pharmaceutical manufacturers and traders shall apply for registration of a new drug only if the new drug:

a) in comparison with existing drug/drugs used for the same conditions:

   i has an equal or superior benefit/risk ratio **or**
   ii has equal or better pharmaceutical properties **or**
   iii can be marketed at a lower price

(b) is recommended for a condition for which no suitable drug treatment is available.

Article 6: Pre-registration clinical trials of new drugs

6.1 No new drug comprising of a single or more than one pharmaceutically active substance may be tested on human beings without formal and written permission from national, regional or international public health authorities.

6.2 Clinical trials of new drugs on human beings will only be permitted for products which have been accurately tested in experimental animals. Animal tests will be carried out in accordance with national, or international legislation and must provide, in the case of each new drug, complete information on the main general and organ system directed pharmacological effects; whether such effects may be therapeutically useful or not; on the absorption, distribution, metabolism and excretion of the active substance/substances contained in a drug; on interactions with other drugs in use, environmental chemicals or food; on acute and short-term toxicity for all drugs and on long-term toxicity for such drugs as may be used for extended periods in human beings and on the environmental toxicity of drugs or drug matabolites liable to be excreted by users of the drugs.

6.3 Requirements for animal testing of new drugs before human trials should be unified and internationally standardised.

6.4 Laboratories both within the premises of pharmaceutical manufacturers

or those consulted by manufacturers must be open to inspection by the public health authorities of all countries in which a new drug may be submitted for trial on human subjects.

6.5 Clinical trials of new drugs on human subjects may only be carried out by suitably qualified and experienced researchers who must be qualified physicians, and according to procedures which must be authorised by the public health authorities. The conduct and protocols for the conduct of clinical trials must be open to inspection by public health authorities at any time. Protocols and information on these trials must also be made available to the registration authorities of countries in which a drug, which has been primarily tested in another country, is proposed for marketing.

6.6 Whenever a new drug is tested on healthy human subjects or on patients, the clinical trial must be authorised and monitored by a local "ethical committee" and must be carried out only with the full informed consent of the people and patients concerned. Governments may require written consent in countries in which the majority of the population is literate; and in countries where the majority of the population is not literate, orally, in the presence of a witness. Consent to volunteer to participate in the trial of a new drug can only be given by the subject, not by his/her legal representative. In the case of children and the insane, consent given by a legal representative to the use of a new drug will be accepted only in situations in which there is a serious and nearly certain danger to the life or to the health of the subject which cannot be averted by existing available pharmaceutical products.

6.7 If permission for the clinical trial of new drugs on human subjects has been refused by the competent authorities of one country, any attempts to obtain such permission in other countries may only be undertaken with the disclosure of full information on the previous refusal of permission and submission of all the documents relating to this refusal of permission.

6.8 Drugs which have been banned from sale after being marketed for some time in one country may not be submitted for clinical trials or marketing in another country, unless the competent authorities of the second country are provided with complete information on the reasons for the drug's withdrawal from the market.

6.9 Physicians in charge of clinical trials of a new drug must rapidly be brought up to date with all new findings on the properties of the drug obtained during the time of a study on human subjects.

6.10 Unnecessary duplication of trials of new pharmaceutical products should be avoided. Procedures for pre-registration trials of new drugs should be internationally agreed.

Article 7: Information

7.1 Governments should be responsible for ensuring that objective and consistent information is provided on all pharmaceutical products marketed in the country. This responsibility should cover either the design, provision and dissemination of information or their control.

7.2. All information on pharmaceutical products must be accurate, balanced, objective and complete. It must be presented in such a way as to conform to legal requirements, to defined ethical standards and to standards of good taste. It should not mislead either directly or by implication. Information must be provided in a language readily understandable to the person who will use it.

7.3 All information provided must be based on up-to-date evaluations of all available scientific evidence and must reflect this evidence accurately and clearly. Sources of evidence must be identified.

7.4 Information submitted to registration authorities and other public health authorities should include both all information required by these authorities and all other information which the pharmaceutical

manufacturer possesses which may be relevant to their deliberations.

7.5. The minimum information which must be made available by pharmaceutical manufacturers for all products to be marketed will include:

(i) *package inserts*—a package insert must be added to every package to be sold to a consumer. For drugs sold to public health authorities for distribution, a sufficient number of package inserts for distribution to each potential user must be provided.

For over-the-counter (non-prescription drugs) the package insert must state the name of the drug, the names of all its pharmaceutically active ingredients which must be given as approved international non-proprietary names if such names exist, and the names of all auxiliary pharmaceutical substances.

Furthermore, the package insert must state the indication or indications (use or uses) of a drug and precise instructions for dosage and the spacing of doses in adults, as well as in children of the main age groups. If a drug is not to be used in a certain age group, this must be stated in the package insert.

Furthermore, the package insert must enumerate all major side-effects of the active drug(s) and possible known side-effects of the auxiliary pharmaceutical substances and must instruct the user on what to do if such side-effects occur. Furthermore, warnings of known interactions (instructions as to which drugs or food should not be combined with that particular pharmaceutical product) and precautions (eg drugs not to be used in pregnancy etc) must be enumerated. Package inserts for drugs sold over-the-counter, as well as for prescription drugs or drugs to be distributed by health officials, convey information so that it is readily intelligible to all prospective consumers and not in a language restricted to the prescriber or distributor. Such medical

or scientific terms as are used must be explained in lay language.

For drugs sold without a prescription, the package insert must explain for how long a drug may be taken without consulting a health professional and the period of time after which a health professional must be consulted in the case of lack of effect of the pharmceutical product or after the occurrence of side-effects.

(ii) *Scientific data sheet for the use of physicians and other health professionals.* This data sheet may be written in a language intelligible to its prospective readers, ie physicians or health professionals. It must contain a full description of the pharmaceutical product, listing all active substances by their international non-proprietary name, if such a name exists, and their doses, and must enumerate all auxiliary pharmaceutical substances used. In the case of organic chemicals for which there is no accepted non-proprietary name, chemical names should be given and illustrated by structural formulas. The scientific data sheet should briefly summarise experimental pharmacological and toxicological data on the pharmaceutically active substances used. It must contain a full description of suggested and accepted therapeutic uses of the pharmaceutical product. Suggested uses may only be included if they are substantiated by reliable scientific evidence which must be quoted. Furthermore, there must be a short but complete description of contraindications to use of the pharmaceutical product; precautions over its use; mechanisms of action (if known); known interactions with other pharmaceutical products, chemicals or food and of dosage regimens in adults, as recommended for the different indications. Doses for children of different age groups must also be stated unless the pharmaceutical product is marked: "Not for use in children under the age of....." Doses in the elderly must be stated if they are different from doses in other adults.

The scientific data sheet must include the address/es of the

manufacturers and their representatives or the address of other persons from whom additional information on a pharmaceutical product may be obtained. Futhermore the data sheet must state the address of the manufacturers' representative or the competent national authority to be informed in the event of unforeseen side-effects or interactions.

7.6 All materials containing drug information must be cleared by the national registration authorities which must also be consulted before any changes can be made to subsequent editions of the materials.

7.7 Information must be presented in scientifically acceptable, precise terms. None of the following words—"safe", "effective", "potent", or "cure" should be used without qualification.

7.8 Longer information booklets on a specific pharmaceutical product must include the standard information contained in the scientific information sheet and as much additional information as the manufacturer can provide. The information reproduced should be reliable and its validity must be capable of scientific substantiation by independent experts. Longer information booklets should not be distributed to all potential prescribers or distributors, but only to those who specifically request them after learning of their existence from publicity or promotional material. The contents of information booklets must be modified if registration authorities require amendments.

Article 8: Labelling, package inserts and promotional material

8.1 Pharmaceutical products are either sold to the public for medication (over-the-counter drugs) or sold to the public on prescription from a physician or other health officials, or used by physicians or other health officials on human beings. The intended mode of sale will be clearly indicated on all containers and packaging materials for pharmaceutical products.

8.2 The international non-proprietary name of each pharmaceutically active substance for which such a name exists must be stated prominently on each package insert and on all promotional material. For pharmaceutically active substances for which no accepted non-proprietary name exists, a suggested non-proprietary name should be indicated.

8.3 In countries in which drugs may be sold and prescribed only under their international non-proprietary names, the packages must not bear any trade name for pharmaceutically active substances. However, the information from the manufacturers may refer to trade names used in other countries, specifying the country in which a given trade name is used.

On the packaging material, the names of manufacturers may be mentioned in brackets after the non-proprietary name and in lettering of the same size as that used for the non-proprietary name.

8.4 In countries where drugs may be sold or distributed under protected trade names, non-proprietary names of the pharmaceutically active ingredients must be stated on all packages and promotional materials in a size of lettering not smaller than one half the size used for the protected trade name.

8.5 Each pharmaceutical product belongs to a class and/or a category or a sub-category of therapeutic or diagnostic products. The class and, if relevant, the category or sub-category must be stated on the packaging material.

8.6 Indications for the therapeutic or the diagnostic use of a pharmaceutical product will not be stated on the packaging material but will be enumerated in package inserts and information for health professionals. Only indications approved by the public health authorities, or generally recognised and endorsed by reputable and independent scientific publications will be included.

8.7 Contra-indications against the use of a pharmaceutical product will be mentioned on the packaging material if the use of a pharmaceutical product in certain categories of human beings may endanger their life or severely endanger their health. All other known contra-indications will be explicitly stated in the package inserts and in the information for health professionals.

8.8 The amounts of the active substance(s) and of auxiliary pharmaceutical substances contained in a pharmaceutical product will be stated in package inserts, as well as in information sheets. Only the active substance(s) and their doses must be stated on the packaging material. Active substance(s) will be designated by their international non-proprietary names if and when such names exist. Auxiliary pharmaceutical substances will be designated by names which can be readily identified by physicians, pharmacists or public health officials. The grade of purity of active substances and of auxiliary pharmaceutical substances found in a pharmaceutical product will be identified by reference to a standard list or internationally recognised pharmacopeia.

Article 9: Sales Promotion of pharmaceutical products

9.1 Pharmaceutical products that may legally be sold to the public without a prescription (over-the-counter drugs) may be promoted to the public through advertisements in the press or displayed publicly or by the media but not by direct mailings. All promotional texts must state the non-proprietary names of the pharmaceutically active substances contained in a pharmaceutical product, the approved uses, contra-indications and precautions. All statements used in the promotion must represent strict scientific truth. The texts must be designed in such a manner as to avoid promoting the use of a drug by persons who do not need to take the drug and may be quite as well off without using it. Promotion may suggest the use of one drug rather than of another but must then state scientifically backed

reasons. All promotional material must be cleared by the drug registration authority.

.2 Drugs that may legally be sold only on prescription by physicians or other professionally trained prescribers cannot be advertised publicly and must not be promoted through either advertisements or articles inserted in the lay press or by radio, television or interviews. Promotion must be limited to professional journals and to personally addressed mailings to prescribers; promotion is also permitted in radio or television progammes addressing exclusively a professionally trained audience. Promotion material for advertising to health professionals must include the information required for the scientific data sheet. In promotional material, this data may be summarised or abbreviated. In this case attention should be drawn to the scientific data sheet. All promotional material must be cleared by the drug registration authority.

.3 Pharmaceutical products to be distributed by public health officials may be promoted by them under conditions similar to those outlined above for medical prescribers. All promotional material must be cleared by the drug registration authority.

.4 All promotional material must be modified if registration authorities request an amendment. Any given promotional item may be banned by a ruling from the competent public health authorities.

.5 Pharmaceutical products which may legally be sold only under prescription may be promoted by medical representatives in all countries where medical representatives are allowed to work. Medical representatives must be adequately trained and possess sufficient medical and technical knowledge to present complete, accurate and valid informaion on their company's products. The manufacturer and his representatives are responsible for all statements made by their representatives and may be held liable. Governments may prescribe particular training courses for medical representatives and impose

examinations or other evaluations of their knowledge and their skills. Oral statements made by medical representatives must contain the minimum information required for printed promotional material. The number of medical representatives working for one company in a given country must not exceed one representative per promoted pharmaceutical product per 500 registered physicians or other prescribers.

9.6 Pharmaceutical products to be sold under prescription may be promoted through the organization of scientific meetings, symposia, and sessions with congresses. If more than 50 per cent of the total cost of such meetings is financially supported by a pharmaceutical manufacturer, this fact must be clearly and visibly stated on all programmes, invitations or abstracts. The information displayed must always draw attention to the minimum information required for the scientific data sheets and must be scientifically accurate and presented objectively and in good taste. Entertainment and hospitality offered during promotional meetings must be limited and must be secondary to the main purpose of the meeting. The level of hospitality must not exceed the provision of goods or services which the participants could not afford to buy or might not normally pay for in everyday life.

9.7 Samples of pharmaceutical products may be provided free of charge to prescribers only at their request. All samples must be clearly labelled as samples in such a manner that they can under no conditions be sold.

9.8 Drug samples for clinical trials may be supplied by manufacturers free of charge to physicians only, and only in the framework of a correctly designed therapeutic trial. The conduct of such a trial must be approved by an "ethical committee" responsible for the control of medical experiments on humans in a given institution or region, or else by public health authorities.

Article 10: Pricing, sales and distribution

10.1 With a view to regulating the equitable distribution of drugs throughout the country, the government of that country may fix the maximum price at which a drug shall be sold.

10.2 In order to encourage indigenous technological development, the government shall carefully examine and compare the cost of production of every locally manufactured drug with the landed cost of a similar but imported drug. If the cost of local production is higher than the landed cost of the imported drug, the government may, in order to reduce or eliminate the wide discrepancies in the retail price of these two categories of the same drug, impose a suitable excise tax on the landed cost of the import drug to bring it closer to or on a par with the cost of local production.

10.3 Every importer of a drug shall within fourteen days of the import of a drug make an application to the government in Form 1. (See at end of Article 10). The government may, after taking into consideration the information furnished in Form 1 and examining the cost of production of a similar locally manufactured drug, impose, if necessary, a suitable excise tax on that drug as mentioned in Article 10.2.

10.4 While fixing the cost of production of a locally manufactured drug as mentioned in Article 10.2, the government may take into account the average cost of production of such a drug by an efficient manufacturer and also taking into consideration material cost, labour charges, overhead costs, etc. For the purpose of this article, an efficient manufacturer means a manufacturer:

(i) whose production of a drug in relation to the total consumption of that drug in that country is comparatively large, **or**

(ii) who employs efficient technology in the production of such a drug.

10.5 The government shall fix a maximum retail price for a drug by specifying the maximum mark-up on the cost of production or the landed cost (if applicable landed cost plus an excise duty as described in Article 10.3). The mark-up will include the manufacturers'/importers' margin, transport and distribution costs, promotional expenses and retailers' commission.

10.6 Every manufacturer, importer or distributor of a drug intended for sale shall display an indelible print mark on the label of the container of the drug or the minimum pack thereof offered for retail sale, the maximum retail price of that drug with the words "retail price not to exceed" preceding it.

10.7 No dealer shall sell any drug to any person at a price exceeding the maximum retail price indicated on the label of the container or pack thereof.

10.8 No dealer shall sell loose quantities of any drug drawn from a container of such a drug at a price which exceeds the *pro rata* price of the drug plus five per cent thereof.

10.9 In order to make a limited number of essential drugs easily accessible to the poorer sections of the population, the government may fix a lower mark-up for these compared to the other drugs. For the purpose of this article, the limited number of essential drugs refer to those which are so defined and listed by a competent health authority (eg. Formulary Committee).

10.10 The government may oblige an importer or manufacturer to allocate a minimum percentage of his total annual turnover to import or locally manufacture (whichever is applicable) essential drugs described in Article 10.9.

10.11 The government may oblige a retail distributor to carry always a sufficient inventory of essential drugs referred to in Article 10.9.

10.12 A retail dealer shall maintain a list of all drugs available with him and their prices; this list should be easily accessible to any person wishing to consult the same.

10.13 No importer, whosesaler, or manufacturer shall withhold from sale or refuse to sell to a retail dealer any drug available to him without good and sufficient reasons.

10.14 No retail dealer shall withhold from sale or refuse to sell any drug available to him to a customer wanting to purchase such a drug for which he has a valid prescription or which is sold over the counter.

10.15 An officer authorised by the government may, with a view to securing compliance with this Article or to satisfy himself that the provisions of this Article have been complied with:

(a) enter and search any place;

(b) Seize any drug, along with containers, packages or coverings in which the drug is found, in respect of which he suspects that any provision of Article 10 has been, or is being, or is about to be, contravened.

10.16 When the government, (but not a private trader) imports drugs and the landed cost of an imported drug is lower than the cost of production of a similar drug locally manufactured, the government may purchase the total output from the local manufacturer after fixing the cost of production as described in Article 10.4 and allowing him a reasonable return on his investment and then fix a common pooled wholesale price for both the imported and the locally produced drug.

Form 1

(To be submitted in duplicate by an importer, within fourteen days of the import, for each imported consignment)

1. Name of the company

2. Address of Registered/Head Office/Factory if any

3. Reference to permission given by the drug registration authority for import of the drug

4. Name of the drug

5. Specifications of the drug

6. Country from which the drug is imported

7. Quantity imported (kg/litres/tonnes, etc)

8. C.i.f. value in foreign currency

		Total local currency		Per unit local currency	
a.	Total c.i.f. paid in local currency	.....	.....	.....	.....
b.	Customs duty paid	.....	.....	.....	.....
c.	Clearing charges with full details	.....	.....	.....	.....
,	Landed cost (a + b + c)	.....	.....	.....	.....

(**Note**: The figures given here should be certified by a practising Cost Accountant/Chartered Accountant)

Article 11: Pharmaceutical technology

The general provisions contained in the draft International Code of Conduct on the Transfer of Technology being negotiated in UNCTAD shall apply to all technology transfer transactions in the pharmaceutical sector.

Alternatively this Code should include the following provisions which are in the UNCTAD draft Code.

11.1 The pharmaceutical technology transferred to a developing country should be appropriate to the economic and social development objectives of that country.

11.2 Upon request of the technology acquiring party the technology supplying party shall make arrangements, as far as possible, to unpackage the technology in terms of information concerning the various elements of the technology to be transferred, such as that required for technical institutional and financial evaluation of the offer.

11.3 In a technology transfer agreement specific provisions should be made for the maximum use of locally available resources.

11.4 Technology transfer agreements should not contain restrictive practices which adversely affect the economic and technological development of the acquiring country. These restrictive practices include, among others: grant back provisions; restrictions on research; restrictions on use of personnel; price fixing; restrictions on adaptations; tying agreements; export restrictions; payments and other obligations after expiration of industrial property rights; restriction after expiration of agreement; restrictions on the scope, volume and capacity of production and field of activity; obligation to use trademarks; requirement of the acquiring party to provide equity capital or to allow supplying party to participate in management; unlimited or unduly long duration of transfer agreements; limitations upon the use of imported technology.

11.5 When negotiating, concluding and performing a technology transfer agreement, the parties should observe fair and honest business practices which include among others:

(a) fair and reasonable terms and conditions

(b) provisions of all relevant information

(c) access by the acquiring party during the period of the agreement to any improvements to the technology transferred under the agreement

(d) the right to cease negotiations if, during the negotiations, either party determines that a satisfactory agreement connot be reached

(e) the supplying party shall, to the extent feasible, provide the acquiring party, during the period of the agreement, with spare parts, accessories and raw materials produced by the supplying party for using the technology transferred, particularly where alternative sources are unavailable

(f) the technology suppliers' guarantee that the technology, meets the description contained in the transfer agreement

(g) the technology suppliers' guarantee that the technology, if used in accordance with the description in the transfer agreement, is suitable for the manufacture of goods as agreed upon by the parties and stipulated in the agreement

(h) the supplying party shall provide adequate training to the personnel of the acquiring party or to the personnel designated by it, in the knowledge and operation of the technology transferred, on the terms stipulated in the agreement

(i) the prices, charges or other considerations made for all elements

involved in the transfer of technology transactions shall be distinctly specified for each item

(j) where the acquiring party has no other alternative than to purchase goods and/or services from the supplying party, or from any enterprise designated by it, the prices for such inputs shall be fair and not higher than current world prices for goods or services of the same quality offered on comparable commercial terms and conditions

(k) the supplying party shall be liable for the loss of, damage or injury to property or persons arising from the technology transferred or the goods produced by it, provided that the technology is used as specified in the agreement, or in the absence of such specification, in a technically correct manner.

11.6 Patent protection should not be given to pharmaceutical products or processes.

If however, some form of protection has to be given, only process patents should be granted and adequate safeguards aimed at ensuring satisfactory working of the patented invention should be provided. These safeguards would be to:

(a) specify that importation does not constitute working of the patent;

(b) provide for an expeditious system of compulsory licensing;

(c) use forfeiture or revocation of the patent on specific grounds;

(d) shorten the duration of the patent and use it to ensure satisfactory working of the patented invention.

Article 12: Research and Development

12.1 Since the national pharmaceutical industry in most developing countries is still in its formative stages, governments shall enter the area of research and development by setting up special research and development institutions and linking their activities to production and innovation.

12.2 Pharmaceutical manufacturers, if they are not engaged in research and development activities themselves, and pharmaceutical importers, shall set aside an agreed parcentage of their total turnover for research and development. This money may be credited to the state sponsored research institutions.

12.3 Pharmaceutical manufacturers and traders may be allowed tax relief on their contributions to research and development.

12.4 The governments shall, in view of the requisite manpower and facilities, the small volume of total research effort, and the low research capability in most developing countries, set up appropriate organizations to define the priorities and problems needing research and coordinate the entire research activities between the specialised institutions set up by the government, universities, and institutes of technology.

Article 13: Implementation and monitoring

13.1 Countries which have accepted the Code should take appropriate steps at the national level to meet their commitment to the Code, including the adoption of national legislation, regulations or other suitable measures. National policies and measures, including laws and regulations, which are adopted to give effect to the principles and aims of the Code should be publicly stated, and should apply on the same basis to all those involved in the manufacture and marketing of pharmaceutical products.

13.2 WHO and UNCTAD shall, on request, provide technical support to countries preparing national legislation or regulations or taking other appropriate measures in implementation and furtherance of the principles and aims of this Code.

13.3 Monitoring the application of this Code lies with the governments of the countries acting individually and together with WHO and UNCTAD. Pharmaceutical manufacturers and traders, appropriate non-governmental organizations, professional groups and consumer organizations should collaborate with governments to this end.

13.4 Independently of any other measures taken for implementation of this Code, pharmaceutical manufacturers and traders should regard themselves as responsible for monitoring their marketing practices, according to the principles and aims of this Code and for taking steps to ensure that their conduct at every level conforms to them.

13.5 Non-governmental organizations, professional groups, consumer organizations and individuals concerned should also undertake to draw to the attention of pharmaceutical manufacturers and traders activities which are incompatible with the principles and aims of this Code, so that they can take appropriate action. The appropriate government authority should also be informed.

13.6 Pharmaceutical manufacturers and traders should appraise each member of their marketing personnel of the principles and aims of this Code and of their responsibilities under it.

13.7 WHO and UNCTAD should provide fora for consultations, discussions and exchange of views between countries on matters related to this Code, in particular to its application and greater harmonisation and the experience gained in its operations.

Article 14: Review procedure

WHO and UNCTAD shall submit a report in four years to the World Health Assembly and the United Nations Conference on Trade and Development, reviewing all the aspects of the Code with proposals for the improvement and further development of the Code.

Appendix

The following is a list of material related to drug issues available from VHAI. Unless otherwise stated, these have been prepared by VHAI Staff.

Sl. No.	*Subject*	*Ref. No.*
	General	
1.	What Consumers Can Do	D-10/340(a)
2.	Rational TB Care—A Priority	D-10/344
3.	Our Concern about Drugs	D-9/334
4.	VHAI's Role in TB Care	D-10/344
5.	VHAI and its Role in Low Cost Drugs	D-9/334(a)
6.	Home Remedies and their Role in Reducing Dependency on Institutionalised Medicine —D P Pandey	D-10/343
7.	The Drug Situation in India	D-10/343
8.	Lists of Essential Drugs—A Comparison	D-9/329
9.	The Great Health Robbery	D-9/331(b)
10.	What is Rational Drug Therapy?	D-16/341(d)
	On Hazardous and Irrational Drugs	
11.	Selection of Appropriate Analgesic and Anti-inflammatory Drugs—Dr Ulhas Jajoo	D-9/334(k)
12.	Rational Therapeutics—Dr Ulhas Jajoo	D-10/343
13.	Banning Drugs	D-10/340
14.	Why Amidopyrines Must Go	D-9/334(g)
15.	Using Tetracycline for Children and Pregnant Women	D-9/334(h)
16.	Why Not to Prescribe Anabolic Steroids	D9/334(i)
17.	Scientific Scrutiny of some Over The Counter Drugs—Dr A R Phadke	D-10/342

18.	A Study of Prevalent Diseases in India and Production of some Essential Drugs —Dr J S Majumdar and others	D-9/335(a)
19.	Misuse of Antibiotics—Dr Ulhas Jajoo	D-10/343
20.	Some Painful Facts about A Painkiller called Amidopyrine	D-10/341(d)
21.	"Medicines as If People Mattered"— Special Issue of "Health For the Millions" (April-June 1981)	

On Hormonal Drugs

22.	Are Hormonal Pregnancy Tests Safe?	D-9/331(a)
23.	Review of Supportive Hormone Therapy in Obstetrics	D-9/331(c)
24.	Pregnant with Danger—a Compendium on Hormone Tests	D—10/342(a)
25.	A Brief Review of the Present Situation of the E P Drug Campaign—December '82	D-10/341
26.	The Case against E P Forte—A Review of the Controversy	D-10/341(d)
27.	Reference on E P Tests for Pregnancy	D-10/341(b)

On Diarrhoea

28.	Drugs in the Treatment of Diarrhoea	D-9/334(c)
29.	Diarrhoea—Significance of the Problem	D-9/334(d)
30.	Diarrhoea and Malnutrition	D-9/334(e)
31.	Causes of Diarrhoea	D-9/334(f)
32.	Management of Acute Diarrhoea	D-9/334(h)
33.	Low Cost Drugs: Managing Diarrhoea	D-9/334(a)
34.	The Clioquinol Controversy	D-9/334(a-1)

On the Bangladesh Situation

35.	In Support of Bangladesh's Drug Policy	D-9/334(j)

36. The Bangladesh Ban on Hazardous and Irrational Drugs — D-9/334(j-1)

37. Criteria for Recommended Withdrawal of Products from the Bangladesh Market—Reprint from "Medicines and the Poor in Bangladesh"—Dianna Melrose — D-10/341(d)

38. Gonosasthya Kendra — D-10/341(d)

39. "Bangladesh finds the Right Prescription" Special Issue of "Health for the Millions" (December 1982)

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HEALTH ACTION INTERNATIONAL

Health Action International is an informal cooperating network of some 50 consumer, development action and other public interest groups active in health and pharmaceutical issues.

Health Action International (HAI) was established at a meeting held in Geneva in May 1981 attended by participants from 27 countries.

The main purpose of HAI is to provide an international network to coordinate activities and share ideas and resources among the various participating groups in order to strengthen the work of these groups and to provide the framework for international campaigns on pharmaceutical issues.

An international information centre and clearing house to serve the participants of **HAI** is maintained by the **International Organization of Consumers Unions (IOCU)** at its Regional Office for Asia and the Pacific in Penang, Malaysia.

For further information, please contact:

BUKO Pharma-Kampagne, BUKO (Bundeskongress Entwicklungspolitischer Aktionsgruppen/Federal Congress, of Development Action Groups) c/o Critte Welt Haus, August Bebel Strasse 62, D-4800 Bielefeld 1, West Germany.

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Ms Virginia Beardshaw, IOCU, Emmastraat 9,2595 EG The Hague, Netherlands.

"We live in a world in which violence, waste and manipulation have not only become central elements in our lives but which have become profitable for the merchants of death, the rapists of the earth and those who manipulate our behaviour, our fears and desires....

"We hope Consumer Interpol and the other citizens networks will work to reduce if not eliminate the violence, the waste and the manipulation that characterises so much of our society".

—Anwar Fazal
President, IOCU
1982 Alternative Nobel Prize Winner
at the award presentation ceremony